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Application Number 10/811,793

Filing Date Mar. 29, 2004

First Named Inventor Plachetka

Art Unit 1616

Examiner Name Choi, Frank

Attorney Docket Number

STATEMENT BY APPLICANT
(Use as many sheets as necessary)

INFORMATION DISCLOSURE

Substitute for form 1449/PTO

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Sheet 1 U. S. PATENT DOCUMENTS Pages, Columns, Lines, Where Name of Patentee or **Publication Date** Document Number Relevant Passages or Relevant Examiner Applicant of Cited Document MM-DD-YYYY Initials\* No. Figures Appear Number-Kind Code<sup>2</sup> (F brown) cols. 1 and 4 Sims 02-22-1994 <sup>บร.</sup> 5,288,507 col. 3 Chen 08-22-2000 <sup>US-</sup> 6,106,862 col. 4 Gergely 05-16-1995 US-5,415,870 US-US-IISus. US-US-US-US-USiis. US-US-US-ŪŠ-

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Under the Paperwork R	eduction Act	of 1995, no persons are	e required to respond to a collection	of information unless it contains a valid OMB control number.  Complete if Known
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INFORMATIO	N DIS	CLOSURE	Filing Date	March 29, 2004
STATEMENT	BY A	PPLICANT	First Named Inventor	Plachetka
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(Use as many	sheets as n	ecessary)	Examiner Name	Choi, Frank 1
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Ź		MOORE, Drug treatment of migraine: Part I. Acute therapy and drug-rebound headache, Am Fam Physician, 1997, 2039-48, 56(8), American Academy of Family Physicians, Kansas City, MO	
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	P. C.	, E	. U.S. PAT	ENT DOCUMENTS			,	
Examiner Initial	*. ° 73	Document Number	Date	Name .	Class	Subclass	Filing Da	
SZ	AA I	4,664,915	May 12, 1987	Simonian	424	128	Feb. 21,	1986
	AB							
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30	AH I	CA 1,165,242	Apr. 10, 1984	Canada	A61K	31/605	\	<del> </del>
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PL	AL I	Day, et al., "Eva	lluation of an Enteric Co	ated Aspirin Preparation," Aust	1. N.Z. J. Med. 6	:45-50 (1976)		
	AM 1	Internet Adverti	sement for Migraleve.	(1998)				
	AN I	Material Safety	Data Sheet for Paracetan	nol D.C. (P.G.S.) (2001)	<u> </u>			0.
·	AO 1	Abstract for Pov Compaction."	vder Technology 33:107-	111 (1982), Krycer, et al., "Th	e Role of Intra-	Granular Porc	sity in Pow	vder
	AP I	Abstract for Dri	ug. Dev. Ind. Pharm. 26(0 chnique to Conventional	8):885-889 (2000), Railkar, <i>et o</i> Methods."	zł., "Evaluation	and Comparis	son of a Mo	oist
	AQI	Abstract for Dr	ug Dev Ind Pharm 27(4	4):337-343 (2001), Railkar, et a Dosage Forms of Acetaminoph	al., "Use of a M en."	oist Granulati	on Techniq	ue
龙	AR I		58-8020 reference Alt					
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Examiner	. 7.	All Chan		Date Considered	814/2	005		

				Atty. Docket No.: 7569/8	30993	Appl No.: 1	0/811,793	
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E		\$	U.S. PAT	ENT DOCUMENTS				
Examiner Initial	PADEWAR	Document Number	Date	Name	Class	Subclass	Filing Da	
R	AA I	2,099,402	Nov. 16, 1937	Keller	167	82	Jan. 17,	934
$\neg$	ABI	4,024,279	May 17, 1977	Zor, et al.	424	319	Jul. 24, 1	975
_	AC I	4,235,971	Nov. 25, 1980	Howard, et al.	435	293	Jun. 9, 1	978
	AD 1	4,380,540	Apr. 19, 1983	Poyser, et al.	424	233	Jan. 18,	1982
	AE I	4,999,226	Mar. 12, 1991	Schock, et al.	424	472	Apr. 27,	1989
	AF I	5,037,823	Aug. 6, 1991	Jones, et al.	514	222.8	Dec. 15,	1989
	1	5,055,306	Oct. 8, 1991	Barry, et al.	424	482	Oct. 20,	1988
0.0	AG I	3,033,300		PATENT DOCUMENTS		•		
	T .		TOREIGN				Translat	ion
		Document Number	Date	Country	Class	Subclass	Yes	No
81	AH I	WO 95/22947	31 August 1995	WIPO	A61P	5/04		
	Al l	EP 0 774 253	21 May 1997	ЕРО	A61K	31/165	x	<u> </u>
	AJI	BE 881 967	16 June 1980	Belgium	e <del>070</del>		х	<u> </u>
A	AKI	CA 2,020,018	27 June 1990	Canada	<u>a</u> 61⅓	31/52	<u> </u>	<u> </u>
	1		OTHER PRIOR ART ()	ncluding Author, Title, Date, Pertiner	nt Pages, Etc.)			
R	AL I			1253 (1997).				
	AMI	Translation for	AJI above.					
犯	AN I	STN/CAS onlin		No. 1999161935 (Mandell, C	leveland Clinic Jo	urnal of Medic	cine 66:285	-292
D	AO I	Albibi, et al., N	etoclopramide: Pharma	cology and Clinical Applicati	ion, "Ann. Int. Med	d. 98:86-95 (1	983).	
The	AP I	Cephalalgia 9:2	29-32 (1989).	of Naproxen vs. Placebo in t				
BL	AQ1	(1989).		ions to Metoclopramide and				_
A	ARI	(1994).		eview with Newer Options a				
邦	ASI	Becker, et al., ' Kinetic Study a Language Abs	and Consequences for M	ts of a Combination of Metor ligraine Patients," <i>Arzneimitte</i>	clopramide and Pa elforschung 42:552	aracetamol. R 2-555 (1992) (	esults of a l	Human English
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				Atty. Docket No.: 7569/809	93	Appl No.: 1	0/811,793	
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Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing D If Appro	
3	AA 2	5,155,105	Oct. 13, 1992	Jones, et al.	514	223.5	Jun. 19,	1991
	AB 2	5,437,874	Aug. 1, 1995	Bru, et al.	424	466	Jan. 4, 1	994.
	AC 2	5,573,776	Nov. 12, 1996	Harrison, et al.	424	435	Sep. 8, 1	994
	AD 2	5,681,583	Oct. 28, 1997	Conte, et al.	424	472	Apr. 25,	1995
	AE 2	5,885,616	Mar. 23, 1999	Hsiao, et al.	424	472	Aug. 18	, 1997
SC	AF 2	6,077,539	Jun. 20, 2000	Plachetka, et al.	424	474	Nov. 10	, 1997
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34	AL 2	35:264-269 (19	995).	aneous Sumatriptan with Usual				
	AM 2	Capobianco, et 71:1055-1066		Diagnosis and Pharmacologic	Treatment of	Migraine," Ma	ayo Clin. Pr	roc.
	AN 2	Chabriat, et al. Multicentre Do	, "Combined Oral Lysine ouble-Blind Placebo-Con	: Acetylsalicylate and Metoclop trolled Study," Cephalalgia 14:	ramide in the . 297-300 (1994	Acute Treatme	ent of Migr	aine: A
	AO 2	Chabriat, et al.		Metoclopramide in the Acute			ks: A Revi	ew,"
	AP 2	Chrubasik,et a	l., "Paracetamol and Met	oclopramide in Fixed Combinat	tion," <i>Med. Mo</i>	ontasschr. Pha	rm. 19:110	(1996)
	AQ 2			the Managed Care Formulary,"	Drug Benefit	Trends 8:28-3	0, 33-34, 4	1
-	AR 2	(1996).  Consumer Ass	oc., "Metoclopramide/A	nalgesic Combinations for Migr	raine," <i>Drug a</i>	nd Therapeutic	cs Bulletin	18:95-
1	AS 2	96 (1980).	"Sumatrintan: A Review	y of its Pharmacodynamic and i	Pharmacokine	tic Properties,		
		Efficacy in the	Acute Treatment of Mig	raine and Cluster Headache," L	Trugs 43:110-1	/98 (1992).	<del></del>	
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				Atty. Docket No.: 7569/80993	i	Appl No.: 1	0/811,793	
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Th	AL 3	Diamond, et al.		i-Inflammatory Agents Have a R		eatment of Mi	graine .	
	AM 3	<del></del>		raine," Postgraduage Medicine 8	5:121-124, 1	27-128, 131,	132-134 (1	989).
	AN 3	Eldor, et al., "E	Ergotamine-Metoclopram	ide for Migraine: Is It Enough?,"	Cephalalgia	32:466 (1992	).	
	AO 3	Ellis, et al., "TI	he Efficacy of Metoclopro	amide in the Treatment of Migrai	ne Headach	e," Ann. Emerg	g. Med. 22:1	191-
	AP 3	<del> </del>	Naproxen Formulations,"	Scand. J. Gastroenterol. 24:44-4	7 (1989).			
	AQ 3	Ganzini, et al., Movement Dis	"The Prevalence of Meto orders," Arch. Intern. Me	oclopramide-Induced Tardive Dy d. 153:1469-1475 (1993).	skinesia and	Acute Extrapy	yramidal	
	AR 3	Greiff, et al., "		teractions with Gastrointesinal N	lotility Modi	fying Agents,	" Clin.	
\$	AS 3	Gupta, et al., " Pharmacodyn.	Effect of Metoclopramid 297:158-165 (1989).	e on Gastric Ulceration and Secre	etion in Albi	no Rats," <i>Arch</i>	Int.	
Examiner		Theho		-Date Considered	814	12005		

				Atty. Docket N	o.: 7569/80 <del>9</del> 93		Appl No.: 10	)/811,793	
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	(Use	several sheets if necess	sary)	Filing Date: M	1arch 29, 2004			Translation Yes No  es and Clinical Use," Drugs Fartrate and Paracetamol in g English Language  oramide in the Acute  985).  a in a Health Maintenance  Anaesthesiol. Scand. 37:49-5.	
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	AM 4	Comparison w Abstract).	ith Individual Drugs and	Placebo, Med. P			ne Tartrate and uding English	l Paracetan Language	nol in 
	AN 4	Hughes, "Meto	oclopramide in Migraine	Treatment," Med	. J. Australia 2:5	80 (1977).			
	AO 4	Treatment of N	Migraine," Headache 37	:454-454 (1997).				the Acute	
	AP 4		, "Naproxen Sodium in						
	AQ4	Organization,	" Ann. Pharmacothe <u>rap</u> y	29:231-230 (133	<u> </u>				
	AR 4	Kandler, et al. (1993).	, "Analgesic Action of I	Metoclopramide is	Prosthetic Hip				37:49-53
A	AS 4	Kirby, et al., 'Emptying, an	"Effect of Metoclopram d Mouth-Cecum Transit	ide, Bethanechol, Time," <i>Pharmace</i>	and Loperamide otherapy 9:226-2	on Gastric F 31 (1989).	tesidence Time	e, Gastric	
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5K	AL 5			mulary for the Treatment of H		lache 35:225-2	227 (1995).	
	AM 5	Kumar, "Rece 9:339-348 (19		Management of Migraine and	Cluster Heada	ches," J. Gen.	Intern. Med	<i>t</i> .
	AN 5	Manniche et d		es of the Individual Constituen 9:153-156 (1984).	ts of an Aspirin	-Metoclopram	ide Combi	nation
	AO 5			ists and Other Agents in Acute	: Migraine," Ad	vances in Head	dache 15:6	-81
	AP 5		atment of Intractable Hea	daches," Neurology 36:101 (1	986).			
	AQ 5	Ottervanger, "	Ketorolac for Severe Mi	graine," <i>Med. Sci. Bul. 26</i> :49 (	1994). 			
	AR 5	Peroutka, "Be	yond Monotherapy: Rati	onal Polytherapy in Migraine,	" Headache 38:	18-22 (1998).		
1	AS 5	Peroutka, "Do	opamine and Migraine,"	Neurology 49:650-656 (1997).				
Examine	r	Sinh Cha		Date Considered	8/4/7	1009		

				Atty. Docket No.: 7569/80993 Appl No.: 10/811,793				•		
LIST O	F REFERI	ENCES CITED	BY APPLICANT	Applicant(s) Plachetka,	et al.					
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			OTHER PRIOR ART (I	ncluding Author, Title, Date, Pertinent Pa	ges, Etc.)					
50	AL 6	Pfaffenrath, et	al., "Analgesics and NS	AIDs in the Treatment of the Ac	ute Migraine	Attack," Ceph	alalgia 15:1	4-20		
	AM 6	Pini, et al., "D	visposition of Naproxen a	After Oral Administration During	and Between	Migraine Atta	acks," Head	ache		
	AN 6	Blocker at al	33:191-194 (1993).  Plosker, et al., "Sumatriptan: A Reappraisal of Its Pharmacology and Therapeutic Efficacy in the Acute Treatment of Migraine and Cluster Headache," Drugs 47:622-651 (1994).							
	AO 6	Dundaling at a	Pradalier, et al., "Treatment Review: Non-Steroid Anti-Inflammatory Drugs in the Treatment and Long-Term Prevention of Migraine Attacks," Headache 28:550-557 (1988).							
	AP 6	Pryse-Phillip	Pryse-Phillips, et al., "Guidelines for the Diagnosis and Management of Migraine in Clinical Practice," Can. Med.							
-	AQ 6	Ross-Lee, et	Assoc. J. 156:1273-1287 (1997).  Ross-Lee, et al., "Single-Dose Pharmacokinetics of Metoclopramide," Eur. J. Clin. Pharmacol. 20:465-471 (1981).							
+	AR 6	Ross-Lee, et	Ross-Lee, et al., "Aspirin Pharmacokinetics in Migraine. The Effect of Metoclopramide," Eur. J. Clin. Pharmacol.							
1	AS 6	Saadah et al	24:777-785 (1983).  Saadah, et al., "Abortive Migraine Therapy with Oral Naproxen Sodium Plus Metoclopramide Plus Ergotamine Tartrate With Caffeine," Headache 32:95-97 (1992).							
Examin	er	Tartrate Will	Catterne, Treatment 31	Date Considered S/ T/200\$						

				Atty. Docket No.: 7569/80993 Appl No.: 10/811,79						
LIST OF	REFERE	NCES CITED I	BY APPLICANT	Applicant(s) Plachetka, et al.						
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			OTHER PRIOR ART	Including Author, Title, Date, Pertin	nent Pages, Etc.)					
	AL 7	Scherl, et al., "	Comparison of Dihydro	ergotamine with Metoclopra che 35:256-259 (1995).	amide Versus Mer	peridine with Pr	omethazine in the			
	AM 7	Schwarzberg,	"Application of Metoclo	pramide Specificity in Migr	raine Attacks Thea	ks Theapy," Headache34:439-441				
	AN 7	Scott "Dihydi	(1994).  Scott, "Dihydroergotamine: A Review of Its Use in the Treatment of Migraine and Other Headaches," Clin.  Neuropharmacology 15:289-296 (1992).							
	AO 7	Sevelius, et al	., "Bioavailability of Na	ationship to Clinica	nship to Clinical Analgesic Effects," Br. J. Clin.					
	AP 7	Silberstein, "I	259-263 (1980). Migraine Symptoms: Re	ported Migraineur						
-	AQ 7	Tfelt-Hansen	Tfelt-Hansen, et al., "The Effectiveness of Combined Oral Lysine Acetylsalicylate and Metoclopramide Compared with Oral Sumatriptan for Migraine," Lancet 346:923-926 (1995).							
-	AR 7		Tfelt-Hansen, et al., "Kombinationen af Oral Lysin-Acetylsalicylat og Metoclopramid Sammenlignet Med Oral Sumatriptan i Behandlingen af Migraeneanfald," Videnskab og Praksis 158:6345-6349 (1996) (including English							
1	AS 7		, urcc	letoclopramide and Aspirin ( nd Study," <i>Cephalalgia 4</i> :10	(Migravess) Versu 7-111 (1984).	s Effervescent	Aspirin or Placebo			
Examin	ner ·	JH ()		Date Considered	8/4/	/200 S				

					Atty. Docket No.: 7569/80993 Appl No.: 10/811,793					
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	AK	L	OTHER PRIOR ART (I		g Author, Title, Date, Pertinent Page	s, Etc.)	·			
TV	AL 8	Tfelt Hansen "	A Double-Blind Study o	f Met	oclopramide in the Treatmer		e Attacks," J.	Neurol.		
	AM 8	Thomson "A S	Neurosurg. Psychiatry 43:396-371 (1980).  Thomson, "A Study to Compare Oral Sumatriptan with Oral Aspirin Plus Oral Metoclopramide in the Acute Treatment of Migraine," Eur. Neurol. 32:177-184 (1992).							
	AN 8	Todd, et al., "N States," Drugs	Todd, et al., "Naproxen: A Reappraisal of Its Pharmacology, and Therapeutic Use in Rheumatic Diseases and Pain States," Drugs 40:91-137 (1990).							
	AO 8	Pharmac. 17:6	Tokola, et al., "Effects of Migraine Attack and Metoclopramide on the Absorption of Tolfenamic Acid, Br. J. Clin. Pharmac. 17:67-75 (1984).							
	AP 8	Attacks," Ceph	Tokola, et al., "Tolfenamic Acid, Metoclopramide, Caffeine and Their Combinations in the Treatment of Migraine Attacks," Cephalalgia 4:253-263 (1984).							
	AQ8	2:57-63 (1975)	Volans, "The Effect of Metoclopramide on the Absorption of Effervescent Aspirin in Migraine," Br. J. Clin. Pharmac. 2:57-63 (1975).							
	AR 8	<i>36</i> :493-502 (1	Von Seggern, et al., "Cost Considerations in Headache Treatment Part 2: Acute Migraine Treatment," Headache 36:493-502 (1996).							
8	AS 8	Welch, "Drug	Therapy of Migraine," A	lew E	ngland J. Med. 329:1476-141	33 (1993).				
Examin	<u>er</u>	Tach	el_		Date Considered	8/4/	2005			

				Atty. Docket No.: 7569/80993 Appl No			o.: 10/811,793				
	F REFE	RENCES CITED	BY APPLICANT	Applicant(s) Plache	etka, et al.						
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				cluding Author, Title, Date, Pertine							
N	AL9	Current Clinical	Experience," Cephalalge	Headache - Their Managem ia 15:337-357 (1995).							
A	AM9	Wright, et al., "	Wright, et al., "Linearity of Metoclopramide Kinetics at Doses of 5-20 mg," Br. J. Clin. Pharmac. 26:469-473 (1988).								
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